510(k) Summary

Contact: Mr. Justin Eggleton
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Washington, DC 20005
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Date Prepared: August 23, 2013

AUG 2 8 2013

Device Trade Name: STALIF X™

Manufacturer: Centinel Spine, Inc
900 Airport Road, Suite 3B
West Chester, PA 19380

Classification: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Code: OVD

Indications For Use:
The STALIF X™ is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open lateral approach.

The STALIF X™ is required to be used with supplementary fixation systems (e.g., pedicle screws) that have been cleared for use in the lumbar spine.

The STALIF X™ system should be used with bone grafting material (autograft only).

Device Description:
The STALIF X™ is a radiolucent intervertebral body fusion device and unicortical cancellous bone screws intended to be used with supplemental fixation. The device is manufactured from PEEK Optima LT-1 or Zeniva ZA PEEK per ASTM F2026 and titanium alloy (Ti6Al4V) per ASTM F136.

Predicate Device(s):
STALIF X™ was shown to be substantially equivalent to the previously cleared STALIF devices (K073109, K101301), Integra Vu aPOD-L (K112986), and Pinnacle Infill (K121733, K103729). The subject device has similar indications for use, design, function, and materials used.

Performance Standards:
Testing performed indicate that the STALIF X™ is as mechanically sound as predicate devices. Testing included static compression, static torsion, static compression-shear, dynamic compression, dynamic torsion, dynamic compression-shear, expulsion, and subsidence per ASTM F2077, F2267, and F-04.25.02.02.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

Centinel Spine, Incorporated
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K130461
Trade/Device Name: STALIF X ™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: July 30, 2013
Received: July 31, 2013

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130461

Device Name: STALIF X™

The STALIF X™ is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open lateral approach.

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices